REMARKS

Reconsideration and allowance are respectfully requested in view of the foregoing amendments and the following remarks.

Upon entry of this Amendment, claims 23-33, 125, and 126 are pending in the application. Claims 1-22, 34-80, and 86-90 have been cancelled without prejudice or disclaimer. Claims 125 and 126 have been added. Applicants reserve the right to pursue these cancelled claims in a continuation application.

Figs. 1 and 4 have been amended to overcome drawing objections noted by the Examiner. Formal figures are submitted herewith that incorporate the amendments to Figs. 1 and 4. Withdrawal of the drawing objections is respectfully requested.

The specification has been amended on pages 8 and 10 in order to overcome objections noted by the Examiner. Withdrawal of the specification objections is respectfully requested.

Claims 23-33 are rejected under 35 U.S.C. §103(a) over the current application disclosure of prior art, such as that of Fig. 1, in view of Tenna, U.S. Patent No. 5,080,092, or Holloway, U.S. Patent No. 3,545,436. This rejection is respectfully traversed.

Claim 23 is directed to a mask for delivering breathable gas to a patient. The mask includes: a mask shell having a portion adapted to receive a supply of pressurized breathable gas and a user side; a gusset portion having a first side attached to the user side of the shell and having a second side; a cushion having a first portion constructed and arranged to attach to the second side of the gusset portion and a second portion constructed and arranged to contact a user's face in use and provide a seal between the mask and the user's face; and a headgear constructed and arranged to attach the mask shell to the user. The gusset portion is constructed and arranged such that it can expand and contract within a range of displacement to alter a distance between the mask shell and the cushion. The gusset portion defines a gusset area exposed to the supply of pressurized breathable gas in use such that the supply of pressurized breathable gas acting on the gusset area provides a component of a contact force F_c of the cushion on the user's face. The force F_c is maintained in approximately constant proportion to the supply of pressurized breathable gas and a total force of the mask on the face F_m is maintained within a range of about 35 - 108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask.

Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest the mask as recited in claim 23. In the Office Action, the Examiner notes that Applicants' disclosed prior art does not recite a gusset portion. The Office Action relies on Holloway or Tenna to

teach a gusset portion. The Office Action asserts that it would be obvious to one with ordinary skill in the art to modify the Prior Art discussed in the current application to interpose a gusset between the shell and the cushion for purposes of increasing the seal capability and comfort level.

Admitted Prior Art in view of Tenna

First, the mask of Tenna is a gas mask that includes fittings for filters 5 for inhaling, a return valve 7 for exhaling, and a central filler 8 for food feeding. Accordingly, the gusset portion 15-17 of Tenna, as defined by the Examiner, does not define a gusset area exposed to a supply of pressurized breathable gas in use such that 1) the supply of pressurized breathable gas acting on the gusset area provides a component of contact force F_c of the cushion on the user's face, 2) the force F_c is maintained in approximately constant proportion to the supply of pressurized breathable gas, or 3) a total force of the mask on the face F_m is maintained within a range of about 35 - 108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask, as recited in claim 23. The gas mask of Tenna is not exposed to a supply of pressurized breathable gas in use, and therefore the recited forces F_c and F_m are also not present.

Second, Tenna does not teach or suggest that the gusset portion is constructed and arranged such that the force F_m is maintained, even if both of the recited forces F_c and F_m are present, within a range of about 35–108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas, as recited in claim 23. Tenna is silent to any magnitude of the forces, if any, that are present. To make up for this deficiency, the Examiner takes the position that it is within the scope of the addition of a gusset in the mask of the Prior Art to have requirements of about 35 - 108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask. Moreover, the Office Action asserts that providing gussets will increase comfort and enhance the sealing capabilities so it would be obvious from the force equations that when the gussets are provided they will fall within the above ranges. Since it is unclear whether the Examiner's position is based on inherency or obviousness, Applicants address both positions.

As to inherency, the Examiner would have to show that the contact force F_c in Tenna is necessarily between 35 - 108 grams per gf/cm^2, as claimed. "To serve as an anticipation when the reference is silent about the asserted inherent characteristic, such gap in the reference may be filled . . . . [such] that the missing . . . matter is necessarily present in the . . . reference, and that it would be so recognized by persons of ordinary skill . . . . 'inherency . .

. may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient . . . .'". *See Continental Can Co. USA, Inc. v Monsato Co., 948 F.2d 1264, 1268-69, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).* "The mere fact that a certain thing may result from a given set of circumstances is not sufficient (to establish inherency) . . . (which requires that) the disclosure is sufficient to show the natural result flowing from the operation as taught would result in the performance of the questioned function . . . " *See In re Oelrich, 666 F.2d 578, 581-2, 212 USPQ 323, 326 (CCPA 1981).* The Examiner cannot show that Tenna necessarily operates within the claimed range, so inherency is not an appropriate basis for rejection. In fact, since Tenna does not operate under pressure, Applicants respectfully submit that it is highly unlikely, if not impossible, for Tenna to produce a force in the claimed range.

The claimed force range is also not obvious to one skilled in the art. Applicants have recognized that maintaining a total force of the mask on the face F_m within a range of about 35–108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask improves patient comfort and enhances sealing capabilities. [For example, see page 11, line 24-page 12, line 9, page 16, line 12-page 17, line 9, and page 25, lines 1-10] Specifically, since mask systems need to be worn for long periods of time, comfort is important and it is a particular problem with prior art masks that they are uncomfortable. One aspect of this is the force of the mask on the patient's face. Applicants have recognized that when a mask is constructed in accordance with the features provided in claim 23, the result will be a mask system with improved comfort and sealing capabilities. How can it be obvious to optimize Tenna when it has no teachings in this regard?

As aforesaid, the Office Action asserts that when the gusset of Tenna is provided it will fall within the claimed range. However, a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977). *See, also*, MPEP 2144.05 (II.)(B.). Tenna has not recognized a range of force that directly correlates to improved comfort and sealing capabilities.

Moreover, Applicants' disclosed prior art cannot be modified to provide the gusset of Tenna without the benefit of Applicant's disclosure and impermissible hindsight. *See Grain Processing Corp. v American Maize-Products Co., 840 F.2d 902, 907, 5 USPQ2d 1788, 1792 (Fed. Cir. 1988).* ("It is impermissible to use the applicant's disclosure as a blueprint to

reconstruct the claimed invention out of isolated teachings in the prior art"). Moreover, there is no motivation for "picking" and "choosing" among the various elements of Applicants' disclosed prior art/Tenna, to the exclusion of other elements, to arrive at the claimed combination. *See In re Kamm, 172 USPQ 298, 301, 302 (CCPA 1972).* ("It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art").

It is respectfully requested, therefore, that the rejection of claim 23 under Frater et al. in view of Tenna be withdrawn.

Admitted Prior Art in view of Holloway

Holloway does not teach or suggest that the gusset portion is constructed and arranged such that the force F_c is maintained in approximately constant proportion to the supply of pressurized breathable gas, or that a total force of the mask on the face F_m is maintained within a range of about 35–108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask, as recited in claim 23. There is no disclosure of any pressure requirement over an operating pressure range of the mask in Holloway.

As to inherency, the Examiner cannot rely on possibilities and probabilities. The Examiner would have to show that the contact force F_c in Holloway is necessarily between 35 - 108 grams per gf/cm^2, as claimed. *See Continental Can Co. USA, Inc. v Monsato Co., supra.* "The mere fact that a certain thing may result from a given set of circumstances is not sufficient (to establish inherency) . . . (which requires that) the disclosure is sufficient to show the natural result flowing from the operation as taught would result in the performance of the questioned function . . . " *See In re Oelrich, supra.* The Examiner cannot show that Holloway necessarily operates within the claimed range, so inherency is not an appropriate basis for rejection.

The claimed force range is also not obvious to one skilled in the art. Applicants have recognized that maintaining a total force of the mask on the face F_m within a range of about 35–108 grams per gf/cm^2 pressure of the supply of pressurized breathable gas over an operating pressure range of the mask improves patient comfort and enhances sealing capabilities.

As aforesaid, the Office Action asserts that when the gusset of Holloway is provided it will fall within the claimed range. However, a particular parameter must first be

recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *See In re Antonie, supra,* and MPEP 2144.05 (II.)(B.). Holloway has not recognized a range of force that directly correlates to improved comfort and sealing capabilities. How can it be obvious to optimize Holloway when it has no teachings in this regard?

Also, Applicants' disclosed prior art cannot be modified to provide the gusset of Holloway without the benefit of Applicant's disclosure and impermissible hindsight. S*ee* *Grain Processing Corp. v American Maize-Products Co., supra.* Moreover, there is no motivation for "picking" and "choosing" among the various elements of Applicants' disclosed prior art/ Holloway, to the exclusion of other elements, to arrive at the claimed combination. *See In re Kamm, supra.*

It is respectfully requested, therefore, that the rejection of claim 23 under Frater et al. in view of Holloway be withdrawn.

Dependent Claims

Dependent claims 24-33 are allowable by virtue of their dependence on claim 23 and for their recitation of additional patentable subject matter.

For example, Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the force F_m is maintained within a range of about 40 – 88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas, as recited in claim 24. Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the force F_m is maintained within a range of about 50 – 88 grams per gf/cm^2 pressure of the supply of pressurized breathable gas, as recited in claim 25. Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the operating pressure range is about 4-25 gf/cm^2, as recited in claim 26. Also, Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the expansion and contraction of the gusset portion permits a seal to be maintained between the cushion and the user's face within a range of about plus and minus 8 degrees angular displacement of the mask shell with respect to the user's face, as recited in claim 27. There is no disclosure of any force requirement or range of displacement of the mask in Applicants' disclosed prior art, Tenna, and Holloway. Applicants have recognized these variables as result-effective variables. *See In re Antonie, Supra.*

Further, Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the gusset portion includes a single gusset having a flexible sidewall with a generally

triangular cross-section when not exposed to the supply of pressurized breathable gas that balloons to a generally rounded cross-section when exposed to the supply of pressurized breathable gas, as recited in claim 28. Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest that the gusset portion includes a sidewall having a thickened cross-section at a base of the sidewall, as recited in claim 29. Also, Applicants' disclosed prior art, Tenna, and Holloway do not teach or suggest a mask arrangement that includes a generally rigid backstop attached to the mask shell for contacting a first sidewall portion of the gusset portion to limit movement of the first sidewall portion, as recited in claim 32. The Examiner is simply using Applicants' disclosure as a blueprint to reconstruct the claimed invention. The Examiner has not established a *prima facie* case of obviousness.

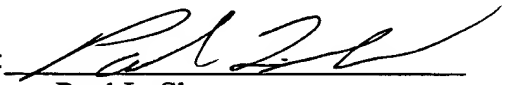
Claims 125 and 126 have been added. Entry and allowance of these new claims is respectfully requested. For example, Tenna and Holloway do not teach or suggest a nasal mask, as recited in claim 125. The mask in Tenna and Holloway is a face mask. Also, Tenna and Holloway do not teach or suggest a CPAP mask, as recited in claim 126.

All rejections and objections have been addressed. It is respectfully submitted that the present application is now in condition for allowance, and a notice to that effect is earnestly solicited.

Should there be any questions or concerns regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,

Pillsbury Winthrop LLP

By: 

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